

COMMISSIONER FOR PATENTS United States Patent and Trademark Office Washington, D.C. 20231

JUL 3 1 2001

George W. Johnston HLR Technology Corporation Patent Law Department 340 Kingsland Street Nutley NJ 07110

Re:

Patent Term Extension

Application for U.S. Patent No. 4,598,089

Dear Mr. Johnston:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,598,089 for a period of five years. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Ferriter

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

cc:

David T. Read

Health Assessment Policy Staff

Acting Director Health Assessment Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852

RE: XENICAL (orlistat)

FDA Docket No.: 00E-1413

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4,598,089

(45) ISSUED : July 1, 1986

(75) INVENTOR : Paul Hadvary, et al.

(73) PATENT OWNER : HLR Technology Corporation

(95) PRODUCT : XENICAL® (orlistat)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,598,089 based upon the regulatory review of the product XENICAL® (orlistat) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) Five years

from June 18, 2004, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the United States Patent and Trademark Office to be affixed this 30th day of July 2002.

JAMES E. ROGAN

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office